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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/347,315	07/02/1999	NARESH TALWAR	RLL-1.1US	3678

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EXAMINER	
WARE, TODD	

ART UNIT	PAPER NUMBER
1615	23

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/347,315	Applicant(s) TALWAR ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/152,932* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of response filed 9-5-02 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-5-02 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term viscolyzing agent is unclear, since no definition is provided as to whether the agent is meant to increase or decrease viscosity. Furthermore, it appears the term may be used contrary to applicant's intent. "-Lyzing" connotes "breaking" or "decreasing" such as in the word "hydrolyze. " However, it appears applicant intends to increase viscosity with the "viscolyzing agent," since the disclosed viscolyzing agents

are various gums. Clarification is requested. The examiner suggests amending the claim with "viscosity enhancing agent" to overcome this rejection, if applicant's intent is to increase viscosity.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation therapeutic drugs, and the claim also recites chemotherapeutic, antibiotic, anti-cancer, etc which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-26 and 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (5,292,518; hereafter '518).

8. '518 teaches prolonged-release drug tablet formulations comprising poly-uronic acids, gums, carbonates, crosslinked polyvinylpyrrolidone, and edible organic acids, wherein the formulations provide controlled release in the stomach and intestines (C2, L18-22; C5, L58-C6, L7; C6, L14-17, 61-C7, L14; Examples). '518 teaches that the active compound is not critical, but that antihistamines may be incorporated into the composition. Also, it is the position of the examiner that since the mixture is blended together that the mixture of '518 is homogenous. '518 teaches the ranges or ingredients of the instant application.

Response to Arguments

9. Applicant's arguments filed 9-5-02 have been fully considered but they are not persuasive. Applicant argues that '518 does not teach or make obvious the instant invention, since '518 does not teach the limitation that the composition provides spatial control of drug delivery. This is not found persuasive since '518 teaches that, as in the case of aspirin, the "gel-plug" insulates the release of the drug and minimizes the caustic effect of the aspirin and allows the drug to leach out of the composition as the dosage form gel hydrates and passes through the gastrointestinal tract (C 7, lines 34-43; Example 1). Thus, '518 indeed provides spatial control of drug release in the gastrointestinal tract. Applicant also states that '518 expressly rejects the use of polyvinylpyrrolidone and therefore leads away from the instant claimed invention.

Presumably, Applicant is referring to the requirement of cross-linked polyvinylpyrrolidone in instant claim 12. In response, Applicant is describing the lack of success of the art prior to '518, since the section of '518 Applicant references is in the background of '518. In fact, '518 teaches the specific inclusion of cross-linked polyvinylpyrrolidone in Example 2.

10. Claims 1-6, 9-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chauhan et al (5,597,844; hereafter '844).

11. '844 teaches tablet compositions of cimetidine, crosslinked polyvinylpyrrolidone, bicarbonates, poly-uronic acids, hydroxypropylmethylcellulose, and gums (C2, L43-C3 L15; Examples). The compositions of '844 float on the contents of the stomach and are blended together in a dry powder mix. It is the position of the examiner, in the absence of unexpected results, that it would be obvious to one skilled in the art to substitute cimetidine with ranitidine, since both are H2-antagonists with the reasonable expected result of blocking H2-receptors in an effort to treat stomach ulceration.

Response to Arguments

12. Applicant's arguments filed 9-5-02 have been fully considered but they are not persuasive. Applicant first argues that '844 teaches granules and does not meet the requirement of the instant claims that the pharmaceutical composition is in the form of tablets or capsules. In response, applicant is directed to column 4, lines 9-15 and Examples 4-7 for the teaching of '844 that the compositions are in the form of tablets. Applicant also argues that the instant claims are restricted to extended release

formulations whereas '844 provides an immediate release formulation and is therefore non-analogous. However, applicant's interpretation of the claims is not agreed with. The instant claims require a controlled drug delivery system... that provides a combination of temporal and spatial control of drug delivery. The instant claims do not recite that the formulation is an extended release formulation nor do they recite a specific time period for release of drug. They only require that release of the drug is controlled. Indeed, '844 meets this requirement in that the dosage form controllably releases the drug in the manner taught in '844. Applicant has cited *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992) where it was held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. In the instant case, it is the position of the examiner that '844 is in the field of applicant's endeavor in that it pertains to cimetidine dosage forms that release cimetidine gastrointestinally.

13. Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (5,292,518; hereafter '518) Chauhan et al (5,597,844; hereafter '844) or vice versa.

14. '518 teaches prolonged-release drug tablet formulations comprising poly-uronic acids, gums, carbonates, crosslinked polyvinylpyrrolidone, and edible organic acids, wherein the formulations provide controlled release in the stomach and intestines (C2, L18-22; C5, L58-C6, L7; C6, L14-17, 61-C7, L14; Examples). '518 teaches that the

active compound is not critical, but that antihistamines may be incorporated into the composition. Also, it is the position of the examiner that since the mixture is blended together that the mixture of '518 is homogenous. '518 teaches the ranges or ingredients of the instant application.

15. '844 teaches tablet compositions of cimetidine, crosslinked polyvinylpyrrolidone, bicarbonates, poly-uronic acids, hydroxypropylmethylcellulose, and gums (C2, L43-C3 L15; Examples). The compositions of '844 float on the contents of the stomach and are blended together in a dry powder mix. It is the position of the examiner, in the absence of unexpected results, that it would be obvious to one skilled in the art to substitute cimetidine with ranitidine, since both are H2-antagonists with the reasonable expected result of blocking H2-receptors in an effort to treat stomach ulceration.

16. '518 does not teach the inclusion of hydroxypropylmethylcellulose in the drug tablet formulations. However, based upon the teachings of '844, it would be obvious to one skilled in the art to include hydroxypropylmethylcellulose in an effort to modulate the viscosity of the composition. While '518 teaches the inclusion of poly-uronic acids, it is not clear whether '518 specifically teaches that alginates are poly-uronic acids, since '518 teaches algal polysaccharides. '844, however teaches that alginate is a poly-uronic acid, and it would therefore be obvious to one skilled in the art to substitute alginate for pectin.

17. '844 does not teach the inclusion of edible organic acids in the drug tablet formulations. However, based upon the teachings of '518, it would be obvious to one

skilled in the art to include edible organic acids in an effort to modify the flavor of the composition.

Response to Arguments

18. Applicant's arguments filed 9-5-02 have been fully considered but they are not persuasive. Applicant relies upon previous arguments over '518 and '844 alone stating that '844 is a non-analogous reference and that combining the rapid release formulation of '844 with the extended release formulation of '518 destroys the intended functions of each reference and is therefore improper. This argument is not found persuasive. First, '844 is not non-analogous as stated in paragraph 12, *supra*. Second, combination of the references does not destroy the intended functions of the references. The intended function of '844 is to ensure that substantially all of the active ingredient is absorbed in the gastrointestinal region and '518 specifically teaches that the controlled release formulation releases the active agent in the gastrointestinal region. Thus combination of the references maintains release of the active in the gastrointestinal region and the intended functions of the references are not destroyed.

Response to Amendment

19. The Declaration under 37 CFR 1.132 filed 11-29-00 is insufficient to overcome the rejection of claims 1-46 based upon 35 U.S.C. 103(a)as set forth in the last Office action because: the scope of the unexpected results are not commensurate with the scope of the claimed invention (see MPEP 716.02(d)).

Conclusion

20. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
November 29, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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